REMARKS

This amendment and response is filed together with a Request for Continued Examination pursuant to 37 C.F.R. § 1.114, together with the fee for a five-month extension of time. Although a Notice of Appeal was filed in this case on July 31, 2007, Applicants request that the appeal be terminated in favor of continued examination.

After entry of the instant amendment, claims 7 and 10 to 13 will remain pending. Claim 7 has been amended to track the ingredients and dissolution times of the tablets described in Examples 1 and 4, respectively. Claims 8, 9 and 14 have been canceled, without prejudice. No claims have been added.

Applicants respectfully submit that the amendments place the claims in condition for allowance.

Applicants acknowledge and thank the Examiner for the indication that the amendments made in the response filed on November 14, 2006 overcame the rejection under 35 U.S.C. §§ 102(b) and 103(a) over Grebow et al, U.S. Patent No. 5,618,845 ("Grebow"). As the Examiner has correctly surmised, Grebow contains no express disclosure of compositions wherein at least about 5% of the cumulative total of modafinil particles in the composition have a diameter of more than about 250 microns, which also contain colloidal silicon dioxide, crospovidone and povidone, and which also achieve a dissolution rate as recited in the claims submitted in that response.

Applicants wish to clarify a statement made in their prior response regarding Grebow, however. In the response, Applicants noted, *inter alia*, that "Grebow does not describe compositions wherein at least about 5% of the cumulative total of said modafinil particles have a diameter of more than about 250μ. … Grebow teaches that dissolution rate is to be controlled by the use of particles having a particular size distribution, *which is outside the size distribution* recited in the amended claims." Applicants wish to bring to the Examiner's attention claim 7 of RE37,516 (the reissued Grebow patent), which recites that the claimed pharmaceutical composition comprises an amount of modafinil effective to alter a somnolent state of a mammal, that the amount of modafinil is in the form of solid modafinil particles and that the particles have a size distribution wherein at least about 95% of the cumulative total of the modafinil particles have a diameter of less than about 200 microns. In addition,

Claim 13 of RE37,516 (which depends from claim 7) further requires additional modafinil particles in excess of the effective amount. These claims should be interpreted to read on a pharmaceutical composition wherein at least about 5% of the cumulative total of modafinil particles in the composition have a diameter of at least about 200 microns (indeed, the current assignee of the instant application asserted this position during litigation, now settled, involving the reissued Grebow patent). Thus, while the subject matter of the instant applicant is patentably distinct from the compositions described in Grebow, the claimed particle size distributions would nonetheless fall within the scope of certain of the Grebow claims.

Rejection under 35 U.S.C. § 112

In the Office Action dated February 1, 2007, claims 7 to 14 were rejected under 35 U.S.C. § 112 for allegedly failing to meet the written description requirement and omitting essential elements. Applicants respectfully submit that this rejection has been rendered moot by the amendment to claim 7.

Rejection under 35 U.S.C. § 103

In the Office Action dated February 1, 2007, claims 7 to 14 were rejected under 35 U.S.C. § 103 as allegedly obvious over Heacock, in view of Corvari and Rudnic. To the extent that this rejection would be applied to the claims as amended herein, Applicants respectfully traverse.

Claim 7, as amended herein, specifies that at least about 15% of the cumulative total of modafinil particles in the composition have a diameter of more that about 200 μ and more than about 5% of the cumulative total of said modafinil particles have a diameter of more than about 250 μ, while also providing a dissolution rate in 0.1N HCl at 37°C of more than about 90% in 30 minutes. The Office Action cites passages in Heacock describing compositions wherein 20% of the particles have a size less than or equal to 200 microns, and 0-5% of the particles have a size less than or equal to 400 microns. The Office Action does not, however, identify where Heacock describes a composition as recited in the pending claims, having more than 15% of the particles being more than about 200 μ and more than about 5% of the cumulative total of said modafinil particles have a diameter of more than about 250 μ. Thus, the Action fails to provide any motivation or suggestion for the preparation of compositions having the recited particle size distribution.

Combination with Corvari and Rudnic fail to overcome this deficiency. Although the Office Action correctly points out that these references may describe the use of glidants and disintegrants, the Office Action fails to show how the references teach or suggest the claimed compositions. Indeed, Corvari *teaches away* from the use of talc as an excipient (see, e.g, paragraph [0006] and claim 1), which is specifically recited as an ingredient in the amended claims.

Moreover, the Office Action fails to show how any proper combination of the teachings of these references would provide those of ordinary skill in the art with a reasonable expectation that compositions containing the recited ingredients and modafinil particles having the recited particle size distribution could be combined to provide the dissolution rate recited in the amended claims. Accordingly, Applicants respectfully submit that the Office Action fails to establish the *prima facie* obviousness of the claims.

Other Matters

Applicants have made the other amendments suggested in the Office Action.

CONCLUSION

Applicants respectfully submit that the application is now in condition for allowance. A Notice of Allowance for all of the pending claims is requested respectfully.

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